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PATENT

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

Application of: Reichenbach et al.,

Serial No: 09/313,524

Filed: May 17, 1999

For: Epothilones C, D, E and F,  
Preparation and Compositions

Group Art Unit: 1626

Examiner: Robert Gerstl

CERTIFICATE OF MAILING  
UNDER 37 C.F.R. §1.8:

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August 10, 2001



Nabeela R. McMillian

Reg. No. 43,363

Agent for Applicants

#13  
Pharma  
8/17/01  
AE

**RESPONSE TO OFFICE ACTION**  
**DATED JUNE 11, 2001**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This paper is filed in response to a final Official Action mailed from the Patent and Trademark Office on June 11, 2001. This response is being filed August 10, 2001, within 2-months of the mailing date of the Official Action. No fees are believed to be due, however, should any fees be deemed necessary in connection with the filing of this document the Commissioner is hereby authorized to deduct any such fees from Marshall, Gerstein and Borun account number 13-2855.

In light of the amendments and remarks presented below, Applicants request withdrawal of the rejections and favorable reconsider of the application.

Claims 1-4, 15 and 16 are pending in the instant case and stand rejected under 35 U.S.C. §102(e). Applicants traverse the rejections.

The Examiner rejected Claims 1-4, 15 and 16 under 35 U.S.C. 102(e) as allegedly being anticipated by the either U.S. Patent No. 5,969,145 or U.S. Patent No. 6,043,372. Applicants respectfully traverse the rejection. The Examiner reviewed Applicants previous response and maintained the rejection because a translation of the foreign priority papers of the instant application had not been made of record in accordance with 37 C.F.R. §1.55. Attached herewith as Appendix A is a translation of German priority document 196 47 580.5 certified by Dr. Boeters as a true and correct translation. Attached as Appendix B is a translation of German priority document 197 07 506.1 certified by Dr. Boeters as a true and correct translation. In light of these submissions and Applicants response dated April 20, 2001, Applicants believe the rejection under 35 U.S.C. §102(e) is overcome and the claims are now in condition for allowance.

For the Examiner's convenience, Applicants reiterate that the claims of the present invention are novel over the patents cited by the Examiner. U.S. Patent No. 6,043,372 is a divisional of U.S. Patent No. 5,969,145 and as such the specifications of the two patents are substantially identical. U.S. Patent 5,969,145 was filed on September 2, 1997 and depends from U.S. Provisional Application Number 60/027,480 filed September 26, 1996.

The only disclosure of Epothilone C in U.S. Patent 5,969,145 relied on by the Examiner in order to anticipate the claims of the instant invention is found at column 24 lines 1-20 wherein the structures of Epothilone C and D are described, (the corresponding disclosure in U.S. Patent No. 6,043,372 is found at column 23 lines 32-52). U.S. Provisional Application Number 60/027,480 **does not** provide a teaching or suggestion that corresponds to this disclosure in the U.S. Patent 5,969,145. As such, the filing date of U.S. Provisional Application Number 60/027,480 cannot be used as the critical date for disclosure of Epothilone C and D in U.S. Patent 5,969,145 because U.S. Provisional Application Number 60/027,480 could not theoretically have issued with claims directed to Epothilone C or Epothilone D. As such, the effective 35 U.S.C. §102(e) critical date of U.S. Patent 5,969,145 is **September 2, 1997**.

Claim 1 of the present invention is directed to Epothilone C. Claim 4 of the

instant invention is directed to Epothilone D. The instant application claims priority of Federal Rep. Germany application 196 47 580.5 which was filed November 18, 1996 and Federal Rep. Germany application 197 07 506.1 which was filed 26 February 1997. Attached herewith as Appendix A and Appendix B respectively, are English language translation of these documents. The certified copies of these documents were submitted with the previous response. Application 196 47 580.5 describes preparation and compositions of Epothilones C and D. Thus, the claims of the instant invention, directed to Epothilones C and D, are entitled to a priority date of **November 18, 1996**. Thus, Applicants submit that the 35 U.S.C. §102(e) date of U.S. Patent 5,969,145 of September 2, 1997 is antedated by Applicants' earlier filed foreign priority application 196 47 580.5 which described the preparation and compositions of Epothilones C and D in a manner sufficient to support the requirements of 35 U.S.C. §112, first paragraph. As such, Schinzer is not prior art against Claim 1.

Claim 2 describes a specific Epothilone having a structural formula  $C_{26}H_{39}NO_5S$  characterized by specific NMR data indicated in Table 1 of the specification. Neither the formula nor the characteristic data are disclosed by any of the Schinzer documents because none of the Schinzer documents provide a teaching or even suggestion of Epothilone C prior to the priority date of the claims of the instant application. Applicants submit that in the absence of such a disclosure the Schinzer documents cannot anticipate claim 2.

Claims 15 and 16 each ultimately depend from claims 1, 2, 3 or 4. Therefore, Applicants assert that these claims also are not anticipated by either of the Schinzer documents. While the Examiner's rejection was directed at claims 1, 2, 15 and 16, for completeness Applicants believe that the above discussion also addresses any similar rejections that the Examiner may set forth against claims 3 and 4. Specifically, as indicated above claim 3 is directed to Epothilone D. The only reference to Epothilone D in U.S. Patent 5,969,145 is found at column 24 lines 1-20. Applicants foreign priority application 196 47 580.5 fully described the preparation and compositions of Epothilone D before the critical 35 U.S.C. §102(e) date of Schinzer. As such, Schinzer is not prior art against Claim 3.

Claim 4 describes a specific Epothilone having a structural formula  $C_{27}H_{41}NO_5S$  characterized by specific NMR data indicated in Table 1 of the specification. Neither the formula nor the characteristic data are disclosed by the any of the Schinzer documents because none of the Schinzer documents provide a teaching or even suggestion of

Epothilone D prior to the priority date of the claims of the instant application. Applicants submit that in the absence of such a disclosure the Schinzer documents cannot anticipate claim 4.

In light of the above discussions, Applicants submit that neither U.S. Patent No. 5,969,145 nor U.S. Patent No. 6,043,372 are prior art to the claims of the instant invention. As such, Applicants request that the rejection be withdrawn and the claims be reconsidered for allowance.

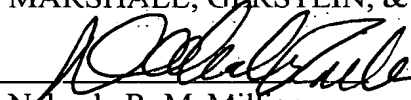
### CONCLUSION

Applicants believe all the claims are now in a condition for allowance. Favorable reconsideration of the application is respectfully requested. The Examiner is invited to contact the undersigned with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,  
MARSHALL, GERSTEIN, & BORUN

August 10, 2001

By:

  
Nabeela R. McMillian  
Registration No. 43,363  
Agent for Applicants  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606-6402  
(312) 474-6300